

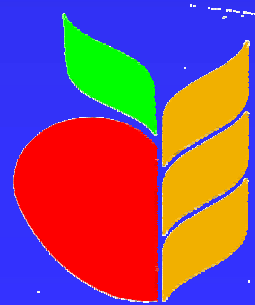
Smallpox Vaccine Operations Seminar



North Dakota Department of Health

Smallpox Vaccine Storage and Handling

Larry A. Shireley, MS,MPH
State Epidemiologist
North Dakota Department of Health



Smallpox Kits



Package Insert

Smallpox Vaccine

Dried, Calf Lymph Type

Dryvax[®]

Dried Smallpox Vaccine

5

Rx only

**DO NOT INJECT INTRAMUSCULARLY (IM), INTRAVENOUSLY (IV), OR
SUBCUTANEOUSLY (SC). FOR CONVENTIONAL SMALLPOX VACCINATION
(SCARIFICATION) ONLY.**

10

DESCRIPTION

Smallpox Vaccine, Dried, Calf Lymph Type, Dryvax[®], is a live-virus preparation of vaccinia virus prepared from calf lymph. The calf lymph is purified, concentrated, and dried by lyophilization. During processing, polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate are added, and trace amounts of these antibiotics may be present in the final product. The reconstituted vaccine has been shown by appropriate test methods to contain not more than 200 viable bacterial organisms per mL.

15

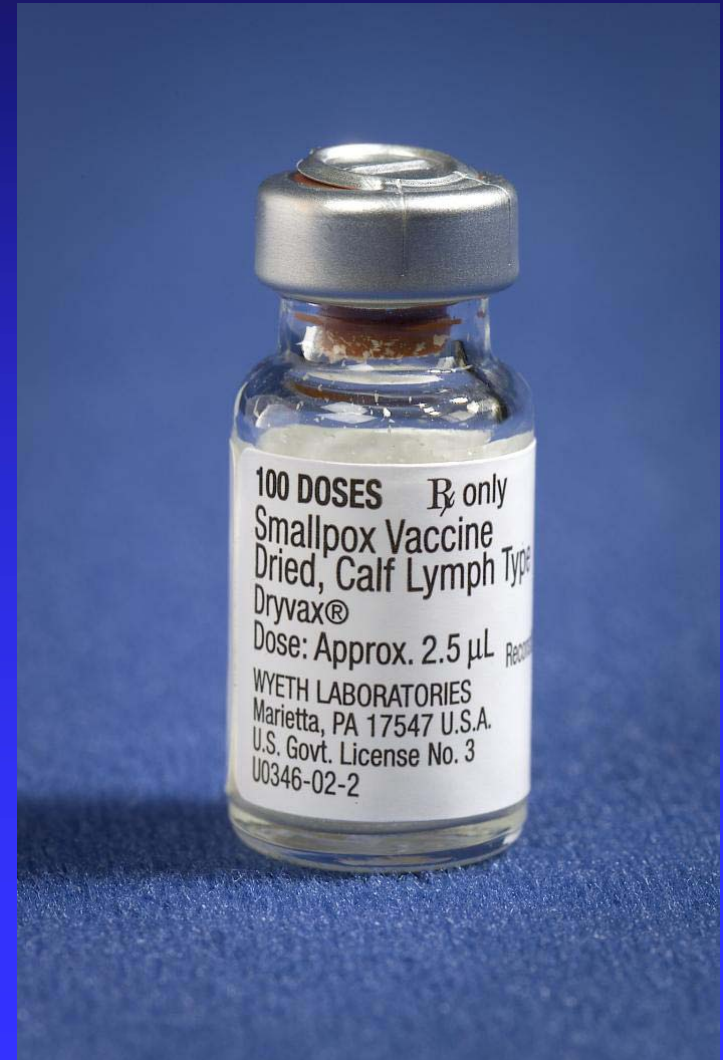
Storage

- 36 – 46° F (2 – 8° C)
 - ◆ DO NOT FREEZE
- Transportation
 - ◆ Powered Coolers
 - ◆ Temperature Monitors
 - ◆ Chain of Custody Forms
- Can keep at room temperature during clinics
- Security

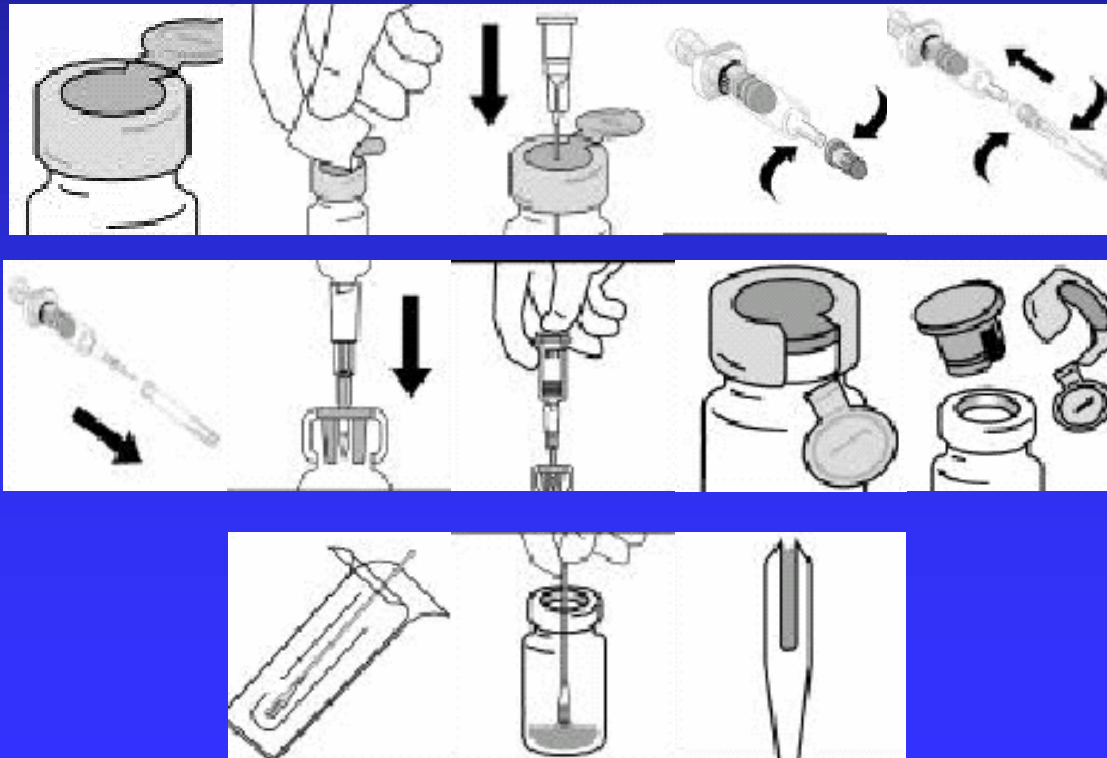


The Vaccine

- DryVax® – Wyeth
- 100 Dose Vials
- Vial Stopper
 - ◆ Natural Rubber



Preparation for Vaccination



Reconstituted Vaccine

- Use for 60 days

- ◆ www.bt.cdc.gov/agent/smallpox/vaccination/pdf/wyeth-dryvax-letter-dec-23-2002.pdf
- ◆ Package insert indicates 15 days

Disposal

- Burn, Boil or Autoclave

VACCINATION CLINICS

Brenda Vossler, RN, CIC
Hospital Coordinator
Division of Bioterrorism
North Dakota Department of Health

Ready, Set, Go

- Smallpox vaccination clinics are scheduled to start the end of February.
- Multiple clinics in each area, 10-21 days apart.
 - ◆ Limits number of staff ill at any one time.
 - ◆ Controls workload as we enter unfamiliar territory.
- Phase I is expected to take 6-9 weeks.

Prior to Clinic Date

- Prospective vaccinees receive the following:
 - ◆ Cover letter from Dr. Gerberding, CDC
 - ◆ Vaccine information fact sheets
 - ◆ Pre-screening tool

Facts Sheets

- Smallpox vaccine information statement (general)
- VIS: Reactions
- VIS: Site Appearance and Care
- VIS: Skin Conditions
- VIS: A weakened Immune System
- VIS: Pregnancy and Breastfeeding
- VIS: For Close Contacts

Pre-Screening

- Each organization will provide pre-screening of potential vaccinees prior to the scheduled vaccination clinic.
 - ◆ Allow time for confidential testing.
 - ◆ Allow time for non-pressured decision making.
- Thorough medical history will be taken at the vaccination clinic site.

Pre-Screening Tool - Conditions

| •Conditions | •Do you have this condition? | •Does a close contact have this condition? |
|---|---|---|
| •1. Currently have cancer, or been treated for cancer within the past 3 months | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| •2. An organ or bone marrow transplant | <ul style="list-style-type: none"> • • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • • YES NO • ↓ • Do not get vaccinated |
| •3. A disease that affects the immune system like lymphoma, leukemia, or a primary immune deficiency disorder | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| •4. An autoimmune disease such as systemic lupus erythematosus (SLE), that may suppress the immune system | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated until you check with your doctor | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated until you check with your contact's doctor |

Pre-Screening Tool - Conditions

| | | |
|--|---|---|
| <ul style="list-style-type: none"> • 5. Currently pregnant or might be pregnant. A <i>pregnancy test is recommended if there is ANY chance you might be pregnant</i> • (When did your last menstrual period begin? ____/____/____) | <ul style="list-style-type: none"> • FEMALES ONLY: • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| <ul style="list-style-type: none"> • 6. Currently breastfeeding | <ul style="list-style-type: none"> • YES NO • ↓ • Delay vaccination until you are no longer breastfeeding | <ul style="list-style-type: none"> • Not applicable |
| <ul style="list-style-type: none"> 7. An allergy to polymyxin B, streptomycin, chlortetracycline or neomycin | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • Not applicable |

Pre-Screening Tool - Conditions

| •Conditions | •Do you have this condition? | •Does a close contact have this condition? |
|--|--|--|
| •8. Had a serious, life-threatening reaction to smallpox vaccine at any time in your life | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| •9. Have Darier's disease, a skin problem that usually begins in childhood | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| •10. Ever given a diagnosis of atopic dermatitis or eczema by a doctor, including as a baby or child | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| •11. Currently have a skin problem that causes significant breaks in the skin surface These problems include burns, severe acne, poison ivy chickenpox, shingles, or other rashes (including those caused by prescription medications) | <ul style="list-style-type: none"> • YES NO • ↓ • Delay vaccination until your skin is healed | <ul style="list-style-type: none"> • YES NO • ↓ • Delay vaccination until your contact's skin is healed |

Pre-Screening Tool - Treatments

| • Treatments | •Are you receiving this medication or treatment? | •Is a close contact receiving this medication or treatment? |
|--|---|---|
| 12. Intravenous steroids or oral steroid pills or capsules (prednisone or related drugs) taken for 2 weeks or longer within the past month | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated •Name and dose of medication: | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated •Name and dose of medication: |
| •13. Drugs that affect the immune system like methotrexate, cyclophosphamide, and cyclosporine, among others, within the last 3 months | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated •Name and dose of medication: | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated •Name and dose of medication: |
| •14. Radiation therapy in the past 3 months | <ul style="list-style-type: none"> • • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • YES NO • ↓ • Do not get vaccinated |
| •15. Chemotherapy for cancer in the past 3 months | <ul style="list-style-type: none"> • • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • • YES NO • ↓ • Do not get vaccinated |
| •16. Currently use steroid drops in your eyes | <ul style="list-style-type: none"> • • YES NO • ↓ • Do not get vaccinated | <ul style="list-style-type: none"> • Not applicable |

Pre-Screening Tool

Additional Questions

- Do you currently have a moderate or severe illness?
- Do you currently have an **itchy red rash** that comes and goes but usually lasts more than 2 weeks, or did you have such a rash as a baby or child?
- Did the itchy rash affect the creases of your **elbows** or **knees**?
- Did you have **food allergies** as a baby or child?
- Above questions are repeated as applicable to a “close contact”

On Arrival to the Clinic

- Prospective vaccinees again receive the documents provided earlier.
- Receive additional information sheets on VIG and Cidofovir.
- Complete Medical History Form with a trained screener.
- Sign Consent statement.

Medical History Form

- Demographics
- Vaccination and medical history
- Current vaccination information and take evaluation
- Consent
- Must be retained at the clinic 5 years or as required by state law, whichever is longer.

Demographics

SECTION A: PATIENT DEMOGRAPHIC INFORMATION

(To be filled out by the patient. Please use ink and print)

Title: _____ First Name: _____ Middle Name: _____
(Mr., Ms., Mrs., Dr., etc.)

Last Name: _____ Suffix (Jr. Sr., M.D., etc.): _____

SSN: _____-_____-_____ Date of Birth: ____/____/____ Gender: Male Female

Street Address: _____ Apt. #: _____

City: _____ State: _____ Zip code: _____

County: _____

Contact Information:

Home Phone: (____) ____-____ Work: (____) ____-____ ext. ____ Cell Phone: (____) ____-____

Fax: (____) ____-____ E-Mail Address: _____

Occupation: _____ Employer: _____

Employer's Address: _____

Ethnicity/Race: ☐ Hispanic or Latino ☐ Asian ☐ African American ☐ Hawaiian

☐ American Indian or Alaskan ☐ White

May we contact you in the future to discuss your vaccination experience? Yes No

Vaccination History

SECTION B: VACCINATION AND MEDICAL HISTORY

(To be filled out by the patient. Please use ink and print)

Vaccination History

Did you ever receive the smallpox vaccine? Use the most recent date if you were vaccinated more than once. I have documentation that I was vaccinated on this date: ____/____/____

____ I recall that I was vaccinated on this date, but I don't have documentation: ____/____/____

____ I was vaccinated in childhood, but I don't know the date.

____ No, I was never vaccinated or I don't know.

Do you have a vaccination scar? ____ Yes ____ No or ____ Don't Know

Did you have any bad reactions to the vaccine (adverse events)? ____ Yes ____ No or ____ Don't know

If yes, please describe the reaction _____

Medical History

Medical History

Have you received chickenpox (varicella) vaccination in the last month?
___Yes ___ No

Are you currently taking medication? ___ Yes ___ No

If yes, please list
medications: _____

Are you sick today? ___ Yes ___ No

If yes, please describe your illness (you may need to wait to be vaccinated
until you get better) _____

Do YOU have any of the following conditions? ____ Yes ____ No

1. Conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers, organ transplant, or agammaglobulinemia.
2. A severe autoimmune disease such as systemic lupus erythematosus (SLE) that may significantly suppress the immune system.
3. Currently taking, or have recently been treated with, immunosuppressive drugs like oral steroids (e.g. prednisone), some drugs for autoimmune disease, or drugs taken after an organ transplant.
4. Taking cancer treatment with drugs or radiation or have taken such treatment in the past three months.
5. Eczema or atopic dermatitis or a history of these conditions, even in childhood or infancy.
6. Other skin conditions that cause breaks in the skin such as an allergic rash, severe burn, impetigo,
7. chickenpox, shingles, or severe acne.
8. Currently being treated with steroid eye drops.
9. Currently pregnant, breastfeeding, or planning to become pregnant in the next month.
10. Ever had a life-threatening allergic reaction to antibiotics polymyxin B, streptomycin, chlortetracycline, neomycin or a previous dose of smallpox vaccine.

IF YOU ANSWERED YES, YOU SHOULD NOT GET THE VACCINE AT THIS TIME.

**Do any of your HOUSEHOLD MEMBERS OR CLOSE
PHYSICAL CONTACTS have any of the following
conditions? ☐ Yes ☐ No**

(Close contacts include anyone living in your household and anyone you have close physical contact with, such as a sex partner. They do not include friends or co-workers.)

The questions that follow are the same as those asked of the individual except regarding steroid eye drops and allergic reaction to vaccine ingredients and breastfeeding.

IF YOU ANSWERED YES, YOU SHOULD NOT GET THE VACCINE AT THIS TIME.

Consent

SECTION D: CONSENT SIGNATURE (TO BE RETAINED BY THE VACCINATION CLINIC)

Date: __/__/__

Patient Name: _____

PVN: _____

I have:

Received, read and understand the Smallpox Pre-Vaccination Information Package, including 1) the Vaccine Information Statement (VIS), 2) the VIS supplements (A-E) on reactions after smallpox vaccination, vaccination site appearance and care, skin conditions, weakened immune system, pregnancy and breastfeeding, and 3) the pre-event screening worksheet;

Considered my own health status as well as the health status of my household members and close physical contacts;

Had the opportunity to discuss my medical concerns with my healthcare provider or a health care provider at the vaccination clinic;

Had the opportunity to obtain a referral to seek confidential laboratory testing for medical conditions that may increase my risk for adverse reactions from the vaccine;

Responded to the questions above to the best of my ability.

I understand the decision to be vaccinated is voluntary and agree to proceed with smallpox vaccination.

CURRENT VACCINATION INFORMATION AND TAKE EVALUATION

(This section will be filled in by clinic staff)

Date: __/__/__

Patient Name:

PVN: _____

DISPOSITION

____ Referred for Vaccination

____ Deferred due to medical contraindications

____ Vaccination refused

Proceed to Vaccination Station

- Vaccination will occur in the upper arm.
- 2-3 punctures with the bifurcated needle for first time vaccinees.
- 15 punctures for re-vaccinees.
- Site will be dressed with gauze/tape dressing or gauze/semi-permeable dressing.
- Post-vaccination and follow up information sheet will be reviewed and given to the vaccinee.

Vaccination Clinic Information

Name:

Contact:

Phone:

Fax:

Address:

Vaccine Batch Information

Vaccine Type:

Program:

Dilution Strength:

Vaccine Lot#:

Vaccine Lot Manufacturer:

Batch #:

Batch Date:

Diluent Lot #:

Diluent Lot Manufacturer:

Referring Organization

Referring Organization _____

Address _____

Date of Vaccination: ____/____/____

Arm inoculated: Left Right

Vaccine Administered by: _____
(please enter first name, last name, and professional suffix (M.D., R.N., etc))

POST-VACCINATION AND FOLLOW-UP INFORMATION SHEET

IMPORTANT: KEEP THIS FORM. BRING IT WITH YOU TO YOUR VACCINATION SITE EXAM.

You have just been vaccinated with Smallpox Vaccine; please do not throw this sheet away. This sheet will serve as your proof of vaccination until you come back to the clinic for your vaccination site exam. On that date, you will get your permanent immunization card.

INTERIM PROOF OF VACCINATION:

Name: _____

Date vaccinated: _____

Clinic: _____

Clinic Telephone No.: _____

APPOINTMENT FOR REQUIRED VACCINATION SITE EXAM:

Date of Appointment: _____

Clinic: _____

Clinic Telephone No.: _____

WHAT TO DO IF YOU THINK YOU ARE HAVING A BAD REACTION TO THE VACCINE:

Call: _____, call your health care provider, or visit an emergency room.

IMPORTANT: DO NOT DISCARD THIS FORM. YOU WILL NEED TO BRING IT WITH YOU WHEN YOU RETURN FOR YOUR VACCINATION SITE EXAM.

Site Observation

- Hospitals and public health units have plans for a trained observer to check or change dressings of patient care providers prior to each shift.
 - ◆ To evaluate for adverse reactions.
 - ◆ To confirm that semi-permeable dressing is intact and drainage contained.
 - ◆ To educate on infection control practices.
 - ◆ Recommended that site care provider is vaccinated.

Vaccination Site Appearance and Care

Site Care Instructions

Follow these instructions until the scab that forms at the vaccination site has fallen off on its own.

WHAT YOU SHOULD DO:

- **When working in a health care setting, cover the vaccination site loosely with gauze, using first aid adhesive tape to keep it in place. Then cover the gauze with a semi-permeable (or semi-occlusive) dressing. Change the bandage at least every 3-5 days in order to prevent build-up of fluids and irritation of the vaccination site. Also wear a shirt that covers the vaccination site** as an additional barrier to spread of vaccinia. (A “semi-permeable dressing” is one that does not allow for the passage of fluids but allows for the passage of air.)
- **When not at work in a health care setting, you need only wear the gauze bandage secured by first aid adhesive tape** over the vaccination site. Change the gauze bandage frequently (every 1-3 days). As an **added precaution** against spread of transmission, **wear a shirt** that covers the vaccination site as well. This is particularly important in situations of close physical contact such as occurs in the household.
- **Wash hands with soap and warm water** or with alcohol-based hand rubs such as gels or foams after direct contact with vaccine, the vaccination site, or anything that might be contaminated with live virus, including bandages, clothing, towels or sheets that came in contact with the vaccination site. This is vital in order to remove any virus from your hands and prevent contact spread.

Site Care

WHAT YOU SHOULD DO:

- Keep the vaccination site dry. Cover the vaccination site with a waterproof bandage when you bathe. Remember to change back to the loose gauze dressing after bathing. If the gauze covering the vaccination site gets wet, change it.
- Put the contaminated bandages in a sealed plastic bag and throw them away in the trash.
- Keep a separate laundry hamper for clothing, towels, bedding or other items that may have come in direct contact with the vaccination site or drainage from the site.
- Wash clothing or any other material that comes in contact with the vaccination site using hot water with detergent and/or bleach. Wash hands afterwards.
- When the scab falls off, throw it away in a sealed plastic bag (remember to wash your hands afterwards).

Site Care

WHAT YOU SHOULD NOT DO:

- **Don't use a bandage that blocks all air from the vaccination site.** This may cause the skin at the vaccination site to soften and wear away. Use loose gauze secured with first aid adhesive tape to cover the site and then cover this with a semi-permeable dressing and shirt when at work in a health care setting.
- **Don't put salves or ointments on the vaccination site.**
- **Don't scratch or pick at the scab.** The vaccination site can become very itchy but you should not scratch it.

Take Evaluation

- Vaccinee will return to clinic site or hospital based site for evaluation of the “take”.
- Will be read as
 - ◆ Major take: visicle or pustule is present.
 - ◆ Equivical take: erythema only.
 - ◆ No take: no response

Take Response

If take response evaluation is going to be conducted at another clinic site, please copy this page and send it to that location.

Take Response Clinic:

Name _____

Address _____

____ Major

____ Equivocal

____ No Take

Additional Comments:

Take Response Exam performed

by: _____

(please enter first name, last name, and professional suffix (M.D., R.N., etc))

Exam Date: ____/____/____

Adverse Events should be recorded in VAERS

Equivocal Take

- Person is sufficiently immune.
- Sub-potent vaccine.
- Improper technique.
- Hypersensitive reaction to vaccine components.
- Impossible to know which reason is cause of this response.

Re-Vaccination

- If no take or equivocal take, re-vaccination is necessary.
- Re-vaccination may occur immediately following the read 6-8 days after the initial vaccination.

CDC Pre-Event Vaccination System Overview

Presented by: Heather Weaver,
RN

Division of Disease Control
ND Immunization Program

Objectives

- Why do we need PVS?
- Who will have access to PVS?
- What does PVS look like?
- Questions?
- What is PVS?

Pre-Event Vaccination System (PVS)

- Developed by CDC for use with the Smallpox Vaccination Program
- A vaccine administration support system
- Web-based system provided to clinics at no cost
- Manages secure data transmission and storage
- Provides pre-defined reports required for evaluation and monitoring of clinics
- Provides secure data views for ad-hoc reporting

PVS Overview

- Administration and Management
 - ◆ Clinic contact information
 - ◆ User roles and security
 - ◆ Digital certificate management
- Vaccine/Diluent Batch Management
 - ◆ Vaccine and diluent lot management through National Pharmaceutical Stockpile
- Patient Management
 - ◆ Patient Demographics
 - ◆ Vaccination History
 - ◆ Current Vaccination
 - ◆ Take Response

Why Is PVS Needed?

- To manage vaccine administration, lot and diluent usage, take tracking
- Existing Registry does not allow for data to be sent to CDC
- Allows data in PVS to be used for aggregate reporting at state and federal levels

Who will have access to PVS?

- State Health Officials
- Local Public Health Units
 - ◆ Data Entry staff
 - ◆ Administrative staff

What does PVS look like?

- Login screen
- Main Menu Screen
- Adding a patient
- Batch Information
- Generating Reports
- Help Screen



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Information Resources Management Office

Pre-Event Vaccination System

Login

User ID

Password

Login

Release I2-20030117C

Pre-Event Vaccination System

Activities

- [Edit Organization](#)
- [Add Program Staff](#)
- [View Program Staff](#)
- [Add Patient](#)
- [Edit Patient](#)
- [Add Vaccine Batch](#)
- [Edit Vaccine Batch](#)
- [Help](#)
- [Logout](#)

Forms

- [Patient Medical History Form](#)

Reports

- [Clinic Daily Activity Reports](#)

Release 12-
20030117C



Pre-Event Vaccination System

Activities

- [Edit Organization](#)
- [Add Program Staff](#)
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- [Patient Medical History Form](#)

Reports

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Release 12-
20030117C

Vaccine Batch

The asterisk (*) denotes a required field.

*Organization

*Vaccine Type

*Program

*Vaccine Lot

*Diluent Lot

*Dilution Strength

*Batch Date

*Vaccinations Per Batch

Save



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Information Resources Management Office

Pre-Event Vaccination System

Activities

- [Edit Organization](#)
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- [Add Patient](#)
- [Edit Patient](#)
- [Add Vaccine Batch](#)
- [Edit Vaccine Batch](#)
- [Help](#)
- [Logout](#)

Forms

- [Patient Medical History Form](#)

Reports

- [Clinic Daily Activity Reports](#)

Release I2-
20030117C

Program Staff

The asterisk (*) denotes a required field.

Title

*First Name

Middle Name

*Last Name

Name Suffix

Save

Activities

- [Edit Organization](#)
- [Add Program Staff](#)
- [View Program Staff](#)
- [Add Patient](#)
- [Edit Patient](#)
- [Add Vaccine Batch](#)
- [Edit Vaccine Batch](#)
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Release 12-
20030117C

Patient Identification

Will this patient be identified? ☒ Yes ☐ No

Patient Demographics

The asterisk (*) denotes a required field.

*Initial PVN

Title

*First Name

Middle Name

*Last Name

Name Suffix

Social Security
Number

*Birth Date (mm/dd/yyyy)

*Gender --Select--

Address Line 1

Address Line 2

City

*State --Select--

Zip

County

*Home Phone - -

Work Phone - - ext

Cell Phone - -

Fax Number - -

Email

*Occupation

Hispanic or Latino
Ethnicity ☐

Asian ☐

African American ☐

Hawaiian ☐

American Indian or
Alaskan ☐

White ☐

Consent To
Photograph ☐

Consent To Survey ☐

Vaccination History

*Vaccine Type

☐ Vaccination Date (mm/dd/yyyy)

☐ Document ☐ Recall

☐ Childhood

☐ Never

Take Response: ☐ Normal
☐ No Take
☐ Scar
☐ Adverse Event
☐ Equivocal

Patient Vaccination

*Organization --Select--

*Batch --Select--

*Referring Organization --Select--

*Vaccination Date

*Administered By --Select--

*Take Response Location --Select--

*Exam Date (mm/dd/yyyy)

*Examiner --Select--

Take Response: ☐ Major

☐ Equivocal

☐ No Take

Adverse Events

Comments

Save and Continue



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Information Resources Management Office

Pre-Event Vaccination System

Activities

- [Edit Organization](#)
- [Add Program Staff](#)
- [View Program Staff](#)
- [Add Patient](#)
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- [Add Vaccine Batch](#)
- [Edit Vaccine Batch](#)
- [Help](#)
- [Logout](#)

Forms

- [Patient Medical History Form](#)

Reports

- [Clinic Daily Activity Reports](#)

Release 12-
20030117C

Clinic Daily Activity Reports

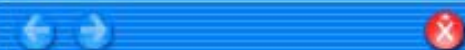
The asterisk (*) denotes a required field.

*Organization Name

*Report Name

*Date (mm/dd/yyyy)

Generate Report



-  Introduction
-  Organizations
-  Patient Record
-  Vaccine Batch
-  Forms
-  Reports
-  Contacting CDC

 Contacting CDC

 Contacting CDC

 Contacting CDC

 Contacting CDC

 Contacting CDC

 Contacting CDC

 Contacting CDC

Introduction

Welcome to the Pre-Event Vaccination System

The Centers for Disease Control and Prevention (CDC) has developed the Pre-Event Vaccination system (PVS) to manage smallpox vaccination data and to track individuals who have been vaccinated against smallpox. The goal of the CDC and the states is to create emergency response teams that can respond to a smallpox outbreak.

A CDC global administrator is responsible for creating user identification numbers and passwords, assigning *roles* to users, and creating records for organizations and clinics that will access PVS. Each user record is associated with one organization. Users can only view patient and vaccination data to which they have been assigned.

PVS includes a Vaccination Roster, which clinics can use to record lot information for vaccine and diluent lots. The clinics can also use the Vaccination Roster to record information for each vaccinated patient. Patient information includes patient demographics, vaccination history, and current vaccination events.

PVS includes the Adverse Events Diary, which is designed to record smallpox vaccination adverse events. The clinics will collect and enter reactions and responses to the vaccination during the four-week period following the vaccination. The Adverse Events Diary helps to correlate the vaccines back to the original vaccine lots or diluent lots. For example, if there a lot of adverse events or low take responses at a specific clinic, the CDC and the state health departments can trace the events back to the original vaccine lot, diluent lot, or vaccinator techniques.

PVS accepts vaccination data from external systems. States that prefer to use their own vaccination systems will be able to export their vaccination data to PVS. CDC sets the guidelines for the states to capture and export the vaccination results.

Questions?

■ Please Contact

Heather Weaver, RN

Division of Disease Control

Immunization Program

701-328-2035

hweaver@state.nd.us

Managing Adverse Events

Stephen P. Pickard MD

Primary Care of Vaccinees

- Likely to see self-limited conditions
 - ◆ Constitutional symptoms
 - ◆ Robust or severe takes
 - ◆ Satellite lesions
 - ◆ Viral cellulitis
- May see inadvertent inoculation (e.g., eye) or household transmission
- Unlikely to see serious reactions

Regional Consultants

- **Contraindications to vaccination**
- **Take**
- **Robust and severe reactions**
- **Wound site care**
- **Infection control procedures**
- **Diagnosis of adverse reactions**
- **Acute management**

Specialists

- ID, Derm, Ophthalmology, Neurology
 - ◆ Ocular implantation, eczema vaccinatum, generalized vaccinia, encephalitis, progressive vaccinia
- Diagnosis
- Management

Specialists

- ID specialists who have assisted NDDoH prepare for vaccination
 - ◆ Dr. James Hargreaves
 - ◆ Dr. Robert Tight
 - ◆ Dr. Kent Martin
 - ◆ Dr. Paul Carson

State or Local Public Health

■ Questions

- ◆ Screening, vaccination risk, site care, take, clinic scheduling, liability, media, vaccine indications, investigational drug protocols, adverse reactions

■ Virologic laboratory

■ VIG or Cidofovir

■ Disease surveillance and reporting

Contacting NDDoH

- Clinical issues (701) 328-2372
 - ◆ Steve Pickard MD
 - ◆ Terry Dwelle, MD, MPHTM
- Vaccination program (701) 328-2378
 - ◆ Heather Weaver
 - ◆ Larry Shireley
- Smallpox program / BT (701) 328-2270
 - ◆ Tim Wiedrich
 - ◆ Brenda Vossler

CDC Consultants

- **Multidisciplinary teams**
- **National smallpox/vaccinia experts**
- **VIG distribution**
- **Clinician Information Line:**

877-554-4625

Obtaining VIG

- You may call NDDoH or Clinician Information Line
- Strongly recommend consultative assistance from ID specialist
- VIG delivered to point of care within 12 hours
- IV product likely, under IND

VAERS Reporting

- All clinically significant vaccine events
- Additional form added for smallpox
- Anyone can report
- Physicians should report
- Possible request for f/u (CDC or FDA)
- On-line reporting: <https://secure.vaers.org/>
- VAERS reporting is not for VIG

Additional Information

www.bt.cdc.gov/agent/smallpox/

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**Smallpox Vaccination and
Adverse Reactions: Guidance
for Clinicians**

Smallpox Communications

Loreeta Leer Frank
Public Information Officer
North Dakota Department of Health

Guiding Principle

The public will need information that will help them minimize their risk

Not Business as Usual

A public health emergency:

- ◆ Triggers a level of public interest and media inquiry that requires a response beyond normal operations and resources.
- ◆ Requires a significant diversion of department staff from regular duties.

Recent Events

- Anthrax concerns ~ 2001
- West Nile virus ~ 2002

Emergencies Are Media Events

- Emergency response would be hampered if media not involved
 - ◆ People rely on media for up-to-date information during an emergency
 - ◆ Media relay important protective actions for the public
 - ◆ Media know how to reach their audiences and what their audiences need

Psychology of a Crisis

Common human emotions may lead to negative behaviors that hamper recovery or cause more harm.

Negative Behaviors

- Demands for unneeded treatment
- Reliance on special relationships
- Unreasonable trade and travel restrictions
- Multiple unexplained physical symptoms

What Do People Feel During a Disaster?

- Denial
- Fear and avoidance
- Hopelessness or helplessness
- Vicarious rehearsal
- Seldom panic

Communicating During a Crisis

When in “fight or flight” moments of an emergency, more information leads to decreased anxiety.

Decision Making During a Crisis

- We simplify
- We cling to current beliefs
- We remember what we previously saw or experienced

How Do We Initially Communicate During a Crisis?

Simply

Timely

Accurately

Repeatedly

Credibly

Consistently

During an Emergency ...

- Don't over reassure
- State continued concern before stating reassuring updates
- Don't make promises about outcomes
- Give people things to do
- Allow people the right to feel fear
 - ◆ Acknowledge fear in self and others

Avoid These Pitfalls

- Jargon
- Humor
- Personal opinions
- Speculation

Effective Messages

- Speed counts
- Facts
- Trusted source

Building Trust in the Message and the Messenger

- Express empathy
- Competence
- Honesty
- Commitment
- Accountability

Public Health's Goal in Emergency Response

To efficiently and effectively reduce
and prevent illness, injury and death
and to return individuals and
communities to normal

Contact Information

Loreeta Leer Frank, public information officer

701.328.1665

rfrank@state.nd.us

Patience Hurley, public information coordinator

701.328.4619

phurley@state.nd.us

Questions?

During this Live program

Call 701-328-2614

or

Send E-mail

Following the Live Program

Call 701-328-2270 or Send E-mail to
twiedric@state.nd.us



North Dakota Department of Health

Smallpox Vaccine Operations Seminar



North Dakota Department of Health